



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2011-0139; FRL-9356-6]

### Residues of Didecyl Dimethyl Ammonium Chloride; Exemption from the Requirement of a Tolerance

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes an exemption from the requirement of a tolerance for residues of Didecyl dimethyl ammonium chloride (DDAC) in or on broccoli grown from treated seeds when applied by immersion. Pace Chemicals Ltd. submitted a petition to EPA under the Federal Food, Drug, and Cosmetic Act (FFDCA) requesting an exemption from the requirement of a tolerance. This regulation eliminates the need to establish a maximum permissible level for residues of DDAC in or on broccoli seed.

**DATES:** This regulation is effective [*insert date of publication in the Federal Register*]. Objections and requests for hearings must be received on or before [*insert date 60 days after date of publication in the Federal Register*], and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2011-0139, is available either electronically through <http://www.regulations.gov> or in hard copy at the OPP Docket in the Environmental Protection Agency Docket Center (EPA/DC), located in EPA West, Rm. 3334, 1301

Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPP Docket is (703) 305-5805. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Tracy Lantz, Antimicrobials Division (7510P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (703) 308-6415; e-mail address: [lantz.tracy@epa.gov](mailto:lantz.tracy@epa.gov).

## **SUPPLEMENTARY INFORMATION:**

### **I. General Information**

#### *A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. Potentially affected entities may include, but are not limited to:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

This listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. Other types of entities not listed in this unit could also be affected. The North American Industrial Classification System (NAICS) codes have been provided to assist you and others in determining

whether this action might apply to certain entities. If you have any questions regarding the applicability of this action to a particular entity, consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of 40 CFR part 180 through the Government Printing Office's e-CFR site at [http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab\\_02.tpl](http://ecfr.gpoaccess.gov/cgi/t/text/text-idx?&c=ecfr&tpl=/ecfrbrowse/Title40/40tab_02.tpl).

*C. How Can I File an Objection or Hearing Request?*

Under FFDCA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2011-0139 in the subject line on the first page of your submission. All objections and requests for a hearing must be in writing, and must be received by the Hearing Clerk on or before [*insert date 60 days after date of publication in the **Federal Register***]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing that does not contain any CBI for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit a copy of

your non-CBI objection or hearing request, identified by docket ID number EPA-HQ-OPP-2011-0139, by one of the following methods:

- *Federal eRulemaking Portal*: <http://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), Mail Code: 28221T, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at <http://www.epa.gov/dockets/contacts.htm>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

## **II. Background and Statutory Findings**

In the **Federal Register** of September 7, 2011 (76 FR 55329) (FRL-8886-7), EPA issued a notice pursuant to section 408(d)(3) of FFDCA, 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide tolerance petition (PP) 0F7747 by Pace Chemicals Ltd., 8321 Willard Street, Burnaby, British Columbia, V3N 2X3. The petition requested that 40 CFR part 180 subpart D be amended by establishing an exemption from the requirement of a tolerance for residues of Didecyl dimethyl ammonium chloride on broccoli grown from treated seeds when applied by immersion. This notice referenced a summary of the petition prepared by the petitioner Pace Chemicals Ltd which is available

in the docket, <http://www.regulations.gov>. A comment was received on the notice of filing. EPA's response to these comments is discussed in Unit VII.C.

Section 408(c)(2)(A)(i) of FFDCA allows EPA to establish an exemption from the requirement for a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the exemption is "safe." Section 408(c)(2)(A)(ii) of FFDCA defines "safe" to mean that "there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information." This includes exposure through drinking water and in residential settings, but does not include occupational exposure. Pursuant to section 408(c)(2)(B) of FFDCA, in establishing or maintaining in effect an exemption from the requirement of a tolerance, EPA must take into account the factors set forth in section 408(b)(2)(C) of FFDCA, which requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue...."

EPA performs a number of analyses to determine the risks from aggregate exposure to pesticide residues. First, EPA determines the toxicity of pesticides. Second, EPA examines exposure to the pesticide through food, drinking water, and through other exposures that occur as a result of pesticide use in residential settings.

### **III. Toxicological Profile**

Consistent with section 408(b)(2)(D) of FFDCA, EPA has reviewed the available scientific data and other relevant information in support of this action and considered its

validity, completeness and reliability and the relationship of this information to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The nature of the toxic effects caused by Didecyl dimethyl ammonium chloride, part of the Aliphatic Alkyl Quaternary group of compounds, are discussed in this unit.

The Aliphatic Alkyl Quaternaries are corrosive and highly irritating to the eye and skin, with moderate acute toxicity by oral, dermal, and inhalation routes of exposure. These chemicals are classified as “not likely” to be human carcinogens based on negative carcinogenicity in rat and mouse feeding studies using doses above the limit dose. There is no evidence of these chemicals being associated with increased susceptibility of infants and children based on two developmental toxicity studies and a 2-generation reproductive toxicity study. Lastly, they are negative for mutagenicity and neurotoxicity. Specific information on the studies received and the nature of the toxic effects from the toxicity studies can be found at <http://www.regulations.gov>. Docket ID Number EPA-HQ-OPP-2006-0338 Toxicology Disciplinary Chapter for the Reregistration Eligibility Decision (RED) for Didecyl Dimethyl Ammonium Chloride (DDAC).

Toxic Endpoints -- For hazards that have a threshold below which there is no appreciable risk, the dose at which no adverse effects are observed (NOAEL) from the toxicology study identified as appropriate for the risk assessment is used to estimate the toxicological level of concern (LOC). However, the lowest dose at which adverse effects of concern are identified (the LOAEL) is sometimes used for risk assessment if no NOAEL was achieved in the toxicology study selected. An uncertainty factor (UF) is applied to reflect uncertainties inherent in the extrapolation from laboratory animal data

to humans and in variations in sensitivity among members of the human population as well as other unknowns. A detailed discussion of EPA's conclusions regarding the toxic endpoints for the Aliphatic Alkyl Quaternaries can be found at 73 FR 37852 (July 2, 2008).

#### **IV. Aggregate Exposures**

In examining aggregate exposure, section 408 of FFDCA directs EPA to consider available information concerning exposures from the pesticide residue in food and all other sources, including drinking water from ground water or surface water and exposure through pesticide use in gardens, lawns, or buildings (residential and other non-occupational exposures).

##### *A. Dietary Exposure*

1. *Food.* Studies have not been submitted measuring residues of Didecyl dimethyl ammonium chloride (DDAC) in broccoli resulting from treatment of broccoli seed. Instead, EPA estimated the DDAC residue concentration that could theoretically result in broccoli heads from the proposed seed treatment use. The number of broccoli seed/pound (lb) is about 144,000 (Oregon State University, Commercial Vegetable Production Guides. Broccoli. *Brassica oleracea* (Italica Group). Last revised August 6, 2004). The proposed treatment rate is 1,200 milligram (mg) DDAC/100 g seed. Seed are to be soaked for 10 minutes and then dried.

The highest seeding rate for broccoli is 1.5 pound per acre (lb/A) (680 g/acre). The lower end of yield in a major broccoli-producing state is 13,000 lb/A in AZ (USDA/NASS; 2003-08). If 680 g seed are treated with 1,200 mg DDAC/100 g, a total of 8.2 g DDAC would be applied to the seed. If all the DDAC is retained by the seed and

the 680 g of seed/acre are planted, the equivalent application rate would be 0.0181 lb DDAC/acre. If all the DDAC were absorbed and translocated to the 13,000 lb of harvested broccoli, the maximum theoretical residue level in broccoli would be 1.4 parts per million (ppm).

The intent of the proposed DDAC seed treatment, however, is to control pathogens on the surface of the broccoli seed which is the major way a number of serious diseases of crucifers are spread and not to control pathogens in soil. Therefore, draining and triple rinsing are conducted to reduce DDAC residues on the seed and there is no intended adsorption (binding) of the DDAC to the seed because the registrant is not claiming residual protection of seed from pathogens in the soil. However, while not intended, it is likely that traces of DDAC would have adsorbed to the seed coat during the 10-minute soaking time.

Taking the draining and rinsing of seed into account, EPA has made a conservative estimate of how much of the theoretical estimate of 1.4 ppm of DDAC on broccoli could actually be present. After seed are soaked in the DDAC solution for 10 min, the solution is drained. EPA estimates that at least 90% of the solution volume will drain off, leaving 10%. This would reduce the theoretical value of 1.4 ppm DDAC in harvested broccoli to 0.14 ppm. This is considered to be reasonable because the treatment solution volume is typically 2 liter (L) for each 100 g of seed and most of the DDAC will be eliminated by draining because of DDAC's solubility in water. Virtually no absorption of solution into the seeds is expected within the 10-minute soaking time. Also, if more than traces of solution were absorbed by seed, this would be detrimental to the seed treatment process because metabolic processes would be activated which would reduce



seed viability and increase rotting. Another 90% of the DDAC from the drained seed is expected to be removed by the three water rinses which would reduce the calculated value of 0.14 ppm to 0.014 ppm. This is reasonable because most of the DDAC is in solution in the film of water between the drained seed and, due to its water solubility; the three rinses are expected to remove any free DDAC remaining.

Although there is no known plant uptake and metabolism studies available for Aliphatic Alkyl Quaternaries similar to DDAC, there are data indicating that DDAC is stable to hydrolysis and will bind tightly to soil. Thus, EPA expects traces of DDAC to be adsorbed (bound) to both the seed coat and the soil surrounding each seed. Considering its immobility, there is little likelihood that DDAC would be absorbed through the seed coat, translocated through the seed and developing shoot, and ultimately concentrated in the harvested broccoli head. This issue was addressed in an earlier EPA decision (K. Leifer, P. Wagner, OPP, RD, 8/1/06 <http://www.epa.gov/opprd001/inerts/dialkyl.pdf>) reassessing the safety of three tolerance exemptions for DDAC when used as an inert ingredient (preservative) in pesticide formulations applied: To growing crops (40 CFR 180.920), postharvest to crops (40 CFR 180.910), or to livestock (40 CFR 180.930). In that decision, EPA concluded that soil application of DDAC to growing crops under 40 CFR 180.920 would not result in systemic uptake by plants because the DDAC would be bound to soil and, therefore, unavailable for plant uptake. Due to the strong binding of DDAC to the seed coat, cellulose, lignin, organic matter, and clay particles, EPA believes that the calculated concentration of 0.014 ppm DDAC in harvested broccoli heads/side shoots is a great overestimate. Given that the calculated concentration for DDAC in broccoli is both very small (0.014 ppm) and considered to be a large overestimate,

dietary exposures to DDAC from use in treatment of broccoli seed are expected to be negligible.

2. *Drinking water exposure.* Contamination of drinking water with Didecyl dimethyl ammonium chloride residues is expected to be negligible as the treatment rate is very low (8.2 g/acre or 0.0181 lb/acre) and the use is expected to be minor. Crucifer seed production is carried out in only a few small areas of the country. In addition, based on data indicating that DDAC is stable to hydrolysis and binds tightly to soil, these residues are expected to be immobilized by components of the soil and sediments. DDAC is classified as a surfactant possessing a charged moiety ( $N^+$ ) and components that are nonpolar/lipophilic (the two 10-carbon alkyl groups). These components provide DDAC with properties allowing it to adsorb both to clay particles (via cation exchange) and organic matter (via hydrophobic attraction of the two alkyl groups). It adsorbs rapidly to soil and sediments but is not readily desorbed. It also binds to cellulose and lignin (organic matter) thus permitting its use as a wood preservative.

The only other Aliphatic Alkyl Quaternaries outdoor uses in addition to growing crops are as algaecides in decorative/swimming pools, antisapstain wood preservative treatment, once-through cooling tower treatment, and oil field uses. The pond and oil field uses are considered to be contained. The other uses are not expected to significantly contaminate drinking water sources. Therefore, the Aliphatic Alkyl Quaternaries contributions to drinking water exposure are considered to be negligible and are not quantified.

It should be noted that the Agency estimated water concentrations resulting from the antisapstain and cooling tower uses to which aquatic animals may be exposed. These

levels were not considered appropriate for use in the drinking water assessment due to the very conservative nature of the models used, that the model estimates runoff/point source concentrations and not water body concentrations, and the fact that the models do not account for dilution.

Specific information on the dietary and drinking water exposure assessments for Aliphatic Alkyl Quaternaries can be found at <http://www.regulations.gov>. Docket ID Number EPA-HQ-OPP-2006-0338 Dietary Risk Assessment on DDAC and Tier 1 Drinking Water Assessment for Alkyl Dimethyl Benzyl Ammonium Chloride (ADBAC) & Didecyl Dimethyl Ammonium Chloride (DDAC).

*B. Other Non-Occupational Exposure*

No residential exposure to DDAC residues is expected from this proposed seed treatment use.

In general, residential exposure assessment considers all potential non-occupational pesticide exposure, other than exposure due to residues in food or in drinking water. Exposures may occur during and after application as a hard surfaces disinfectant (e.g., walls, floors, tables, fixtures), to textiles (e.g., clothing, diapers) to swimming pools and to carpets. Each route of exposure (oral, dermal, inhalation) is assessed, where appropriate, and risk is expressed as a Margin of Exposure (MOE), which is the ratio of estimated exposure to an appropriate NOAEL

Residential exposure may occur during the application of Aliphatic Alkyl Quaternaries to indoor hard surfaces (e.g., mopping, wiping, trigger pump sprays), carpets, swimming pools, wood as a preservative, textiles (e.g., diaper treated during

washing and clothes treated with fabric spray), and humidifiers. The residential handler scenarios were assessed to determine dermal and inhalation exposures. Surrogate dermal and inhalation unit exposure values were estimated using Pesticide Handler Exposure Database (PHED) data and the Chemical Manufacturers Association Antimicrobial Exposure Assessment Study (USEPA, 1999), and the SWIMODEL 3.0 was utilized to conduct exposure assessments of pesticides found in swimming pools and spas (Versar, 2003). Note that for this assessment, EPA assumed that residential users complete all elements of an application (mix/load/apply) without the use of personal protective equipment.

The duration for most residential exposures is believed to be best represented by the short-term duration (1 to 30 days). The short-term duration was chosen for this assessment because the residential handler and postapplication scenarios are assumed to be performed on an episodic, not daily basis.

Based on toxicological criteria and the potential for exposure, the Agency has conducted dermal and inhalation exposure assessments for Aliphatic Alkyl Quaternaries residential use. Specific information on the residential exposure assessment for Aliphatic Alkyl Quaternaries can be found at <http://www.regulations.gov>. Docket ID Number EPA-HQ-OPP-2006-0338 Didecyl Dimethyl Ammonium Chloride (DDAC) Occupational and Residential Exposure Assessment.

### *C. Safety Factor for Infants and Children*

1. *In general.* Section 408 of FFDCA provides that EPA shall apply an additional tenfold (“10X”) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the data base on

toxicity and exposure unless EPA determines based on reliable data that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act safety factor (FQPA SF). In applying this provision, EPA either retains the default value of 10X when reliable data do not support the choice of a different factor, or, if reliable data are available, EPA uses a different additional FQPA SF value based on the use of traditional uncertainty/safety factors and/or special FQPA SFs, as appropriate.

2. *Prenatal and postnatal sensitivity.* There is no evidence that Aliphatic Alkyl Quaternaries result in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental studies or in young rats in the 2-generation reproduction study.

3. *Conclusion.* EPA has determined that reliable data show that it would be safe for infants and children to reduce the FQPA SF to 1X except for assessments addressing inhalation exposure. For inhalation exposure assessments the 10X FQPA SF is retained. Those decisions are based on the following findings:

i. The toxicity database for Aliphatic Alkyl Quaternaries is complete except for a 90-day inhalation toxicity study in the rat which was requested in the Aliphatic Alkyl Quaternary Reregistration Eligibility Document. Due to the absence of the 90-day inhalation toxicity study, a FQPA SF of 10x has been applied to the oral endpoint to calculate inhalation risks in order to be protective of any uncertainties associated with route-to-route extrapolation.

ii. There is no indication that Aliphatic Alkyl Quaternaries are neurotoxic chemicals and there is no need for a developmental neurotoxicity study or additional uncertainty factors to account for neurotoxicity.

iii. There is no evidence that Aliphatic Alkyl Quaternaries result in increased susceptibility in *in utero* rats or rabbits in the prenatal developmental toxicity studies or in young rats in the two-generation reproductive toxicity study.

iv. There are no residual uncertainties identified in the exposure databases. The dietary food exposure assessment was performed based on 10% transfer rate and tolerance-level residues. Similarly conservative Residential SOPs were used to assess post-application exposure to children as well as incidental oral exposure of toddlers. These assessments will not underestimate the exposure and risks posed by Aliphatic Alkyl Quaternaries.

## **V. Cumulative Effects from Substances with a Common Mechanism of Toxicity**

Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

The Aliphatic Alkyl Quaternaries are a group (Group I cluster from PR Notice 88-2) of structurally similar quaternary ammonium compounds that are characterized by having a positively charged nitrogen covalently bonded to two alkyl group substituent’s (at least one C<sub>8</sub> or longer) and two methyl substituent’s. In finished form, these quaternary ammonium compounds are salts with the positively charged nitrogen (cation) balanced by a negatively charged ion (anion). The anion for the quaternary ammonium compounds in this cluster is chloride or bromide. Dimethyl Didecyl ammonium chloride, or DDAC, was chosen as the representative chemical for the Group I Cluster in PR notice

88-2. On that basis, the toxicology database for DDAC is accepted as representative of the hazard for this class of quaternary ammonium compounds.

EPA's risk assessment for the Group I Cluster is based on an assessment of the exposure to all aliphatic alkyl quaternary compounds. Although grouped in 1988 based on structural similarity, a formal determination of common mechanism has not been conducted. The individual exposure scenarios in the DDAC assessments (as well as the aggregate assessment in the RED) were developed by assuming that a DDAC compound was used on 100 percent of the food contact surfaces authorized on the label that could result in human exposure. Thus, the risk assessment for DDAC accounts for exposures to all of the Aliphatic Alkyl Quaternary compounds. The Agency has not identified any other substances as sharing a common mechanism of toxicity with Didecyl dimethyl ammonium chloride.

Didecyl dimethyl ammonium chloride does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, therefore, EPA has assumed that DDAC does not have a common mechanism of toxicity with other substances. For information regarding EPA's efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA's website at <http://www.epa.gov/pesticides/cumulative>.

## **VI. Determination of Safety for U.S. Population, Infants and Children**

Conservative estimates indicate that there is no reasonable expectation that anything greater than negligible residues of DDAC will be present in broccoli as a result of the proposed seed treatment use. EPA has previously. <http://www.regulations.gov>, Docket ID Number EPA-HQ-OPP-2006-0572 determined that risks from aggregate

exposure are safe, 72 FR 51180 (September 6, 2007); 73 FR 37852 (July 2, 2008) this proposed seed treatment use adds essentially zero additional exposure so the prior aggregate risk conclusion remains applicable. The only change in this assessment is the retention of the FQPA 10X safety factor for inhalation risks which makes the level of concern MOEs of 1000 or below. The MOEs for residential handler inhalation risks were all  $\geq 3400$  and thus are not of concern. Adult and child inhalation risks were found to be of concern in the Reregistration Eligibility Document as a result of breathing mist from treated humidifier water; this was the only child's inhalation scenario. To eliminate this risk, Didecyl dimethyl ammonium chloride has been restricted to use in evaporative humidifiers. Evaporative humidifiers, unlike other types of humidifiers, do not generate and expel treated droplets or mist. The Didecyl dimethyl ammonium chloride will volatilize in, at most, negligible amounts from treated water in evaporative humidifiers. Aliphatic Alkyl Quaternaries are salts that are very soluble in water and have a negligible vapor pressure; as a result, they have a very low Henry's Law Constant which means they have a negligible tendency to volatilize from an aqueous solution such as that in treated humidifier water.

Accordingly, in reliance on the previous safety finding, and the determinations made in that rulemaking document and this document, EPA finds that there is a reasonable certainty that no harm will result to the general population or to infants and children from aggregate exposure to Didecyl dimethyl ammonium chloride residues. Further, EPA concludes that the proposed use will not pose a risk under reasonable foreseeable circumstances. Therefore, EPA finds that exempting DDAC from the requirement of a tolerance when used as a broccoli seed treatment will be safe.



## **VII. Other Considerations**

### *A. Analytical Enforcement Methodology*

An analytical method is not required for enforcement purposes since the Agency is establishing an exemption from the requirement of a tolerance without any numerical limitation.

### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDCA section 408(b)(4). The Codex Alimentarius is a joint U.N. Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Codex has not established a MRL for Didecyl dimethyl ammonium chloride in broccoli.

### *C. Response to Comments*

The Agency received one comment in response to the notice of filing for this petition. The commenter stated that they did not approve of the toxic chemical “dimethyl (mercury) amminia chloride” being approved by the Agency.

In response to this comment, the Agency notes that mercury is not a component or degradate of Didecyl dimethyl ammonium chloride. EPA comprehensively evaluated the safety of DDAC in the <http://www.regulations.gov>, Docket ID Number EPA-HQ-OPP-2006-0572. The commenter has provided no basis for EPA to vary from its prior evaluation of the risk posed by DDAC.

### **VIII. Conclusion**

Therefore, an exemption from the requirements of a tolerance is established for residues of Didecyl dimethyl ammonium chloride in or on broccoli grown from treated seeds when applied by immersion.

### **IX. Statutory and Executive Order Reviews**

This final rule establishes a tolerance under section 408(d) of FFDCA in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled *Regulatory Planning and Review* (58 FR 51735, October 4, 1993). Because this final rule has been exempted from review under Executive Order 12866, this final rule is not subject to Executive Order 13211, entitled *Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use* (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled *Protection of Children from Environmental Health Risks and Safety Risks* (62 FR 19885, April 23, 1997). This final rule does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.*, nor does it require any special considerations under Executive Order 12898, entitled *Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations* (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under section 408(d) of FFDCA, such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) do not apply.

This final rule directly regulates growers, food processors, food handlers, and food retailers, not States or tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of section 408(n)(4) of FFDCA. As such, the Agency has determined that this action will not have a substantial direct effect on States or tribal governments, on the relationship between the national government and the States or tribal governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian tribes. Thus, the Agency has determined that Executive Order 13132, entitled *Federalism* (64 FR 43255, August 10, 1999) and Executive Order 13175, entitled *Consultation and Coordination with Indian Tribal Governments* (65 FR 67249, November 9, 2000) do not apply to this final rule. In addition, this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (UMRA) (Public Law 104-4).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act of 1995 (NTTAA), Public Law 104-113, section 12(d) (15 U.S.C. 272 note).

## **X. Congressional Review Act**

The Congressional Review Act, 5 U.S.C. 801 *et seq.*, generally provides that before a rule may take effect, the agency promulgating the rule must submit a rule report to each House of the Congress and to the Comptroller General of the United States. EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to publication of this final rule in the **Federal Register**. This final rule is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 23, 2012.

Joan Harrigan Farrelly,

*Director, Antimicrobials Division, Office of Pesticide Programs.*

Therefore, 40 CFR chapter I is amended as follows:

**PART 180--[AMENDED]**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Section 180.1317 is added to subpart D to read as follows:

**§ 180.1317 Pesticide chemicals; exemption from the requirements of a tolerance.**

An exemption from the requirement of a tolerance is established for residues of Didecyl dimethyl ammonium chloride in or on broccoli resulting from the use of Didecyl dimethyl ammonium chloride as a seed treatment at a treatment concentration of 1200 ppm prior to planting by immersion.

[FR Doc. 2012-19399 Filed 08/07/2012 at 8:45 am; Publication Date: 08/08/2012]